

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB,  
ASTRAZENECA UK LIMITED

(b) County of Residence of First Listed Plaintiff \_\_\_\_\_  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)  
John E. Flaherty, MCCARTER & ENGLISH, LLP

Four Gateway Center, 100 Mulberry Street  
Newark, New Jersey 07102; (973) 622-4444

**DEFENDANTS**

AUROBINDO PHARMA LIMITED and  
AUROBINDO PHARMA USA INC.

County of Residence of First Listed Defendant India  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF  
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question  
(U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity  
(Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                        | DEF                        |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input checked="" type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

**V. ORIGIN** (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

35 U.S.C. § 271

Brief description of cause:

Patent Infringement (ANDA)

**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE Hon. Freda L. Wolfson, U.S.D.J.

DOCKET NUMBER (see attachment)

DATE

05/15/2019

SIGNATURE OF ATTORNEY OF RECORD

s/John E. Flaherty

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

**Civil Cover Sheet Attachment:**

The following captioned actions are related to the matter in controversy because the matter in controversy involves United States Patent Nos. 8,536,206, 8,604,064, and 8,618,142 and the same drug product:

*ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, AND ASTRAZENECA UK LIMITED V. ALKEM LABORATORIES LTD.*, C.A. NO. 18-cv-16399 (FLW) (LHG) (D.N.J).

The undersigned hereby further certifies that the patents-at-issue were the subject of the previous Hatch-Waxman cases before this court, all of which have settled<sup>1</sup>:

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. TORRENT PHARMA INC. AND TORRENT PHARMACEUTICALS LTD.*, C.A. NO. 16-cv-02091 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. MICRO LABS USA, INC. AND MICRO LABS LTD.*, C.A. NO. 15-cv-03376 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. STRIDES PHARMA, INC. AND STRIDES PHARMA GLOBAL PTE LIMITED*, C.A. NO. 15-cv-03378 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. APOTEX CORP. AND APOTEX INC.*, C.A. NO. 15-cv-03379 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. PRINSTON PHARMACEUTICAL INC.*, C.A. NO. 15-cv-03380 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. BRECKENRIDGE PHARMACEUTICAL INC.*, C.A. NO. 15-cv-03382 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. CITRON PHARMA LLC AND MSN LABORATORIES PRIVATE LIMITED*, C.A. NO. 15-cv-03383 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. MYLAN PHARMACEUTICALS INC.*, C.A. NO. 15-cv-03384 (D.N.J);

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<sup>1</sup> The following cases were consolidated into *In re Certain Consolidated Roflumilast Cases*, C.A. No. 15-03375 (FLW) (DEA) (D.N.J).

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. HETERO USA INC., HETERO LABS LIMITED UNIT-III, AND HETERO LABS LIMITED*, C.A. NO. 16-cv-03385 (D.N.J);

*TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. ZYDUS PHARMACEUTICALS (USA) INC.*, C.A. NO. 15-CV-03377 (D.N.J.).